REMARKS

Reconsideration of this application is respectfully requested. To this end, petition is hereby made for a three-month extension of time to respond to the outstanding Office Action mailed October 3, 2008.

Claims 1, 5-56, 58-77 and 80-155 are pending in the application. Upon entry of this Amendment, the second claim numbered 117 and claims 118-154 will be amended to renumber them as claims 118-155, respectively, to correct the numbering error noted by the Examiner in the outstanding Office Action in which two claim 117s were presented in the application. In this regard, the dependencies of such claims have also been changed to reflect the renumbering of such claims. Accordingly, the Examiner's objection to these claims should be withdrawn.

In addition, upon entry of this Amendment, claims 1, 17, 56, 58, 83, 84, 87, 88, 91, 92, 95, 96, 99 100, 103, 104, 107, 108, 112, 117, 122, 127, 132, 137, 142 and 155 will also be amended to eliminate the term "esophagus" from such claims to advance the prosecution of this application.

In the outstanding Office Action of October 3, 2008, the Examiner rejected claims 1, 17-19, 56, 58-60 and 83-155 under 36 U.S.C.§103(a) as being unpatentable over Vincent (USP 5,601,604) in view of Furst (U.S. Pub. No. 20020099438). The Examiner's rejection is respectfully traversed.

In rejecting a claimed invention under §103(a) as being obvious over a combination of references, the Examiner must identify the reason as to why a person of ordinary skill in

the art would have combined the references applied by the Examiner to produce the claimed invention. *See, e.g.,* Memorandum from Deputy Commissioner for Patent Operations to the Technology Center Directors, dated May 3, 2007, commenting on the impact on obviousness rejections under 35 U.S.C. §103(a) of the Supreme Court decision in the case of *KSR Int'l. Co. v. Teleflex, Inc.*, ___ U.S. ___, 127 S.Ct. 1727 (2007), recognizing that "it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed." (Attachment A).

In his §103(a) rejection of claims 1, 17-19, 56, 58-60 and 83-155, the Examiner again argues that "[i]t would be obvious to one of ordinary skill in the art to provide a coating on the elongate structure, as taught by Furst, to Vincent in order to reduce inflammation, infection, irritation, and/or rejection of the device." In his §103(a) rejection of claims 1, 17-19, 56, 58-60 and 83-155, the Examiner further argues that "[a]lthough Furst does not teach a property improving viscoelastic layer, it would have been obvious to one of ordinary skill in the art to provide a layer surrounding the device made of a biocompatible material that reduces the likelihood of injuring or damaging tissue upon contact, such as silicone gel, cellulose gel, or collagen gel." 10/3/08 Office Action, pp. 4-5.

1. The Claimed Invention Is Not Obvious Over Vincent And Furst

Applicant asserts that rejected claims 1, 17-19, 56, 58-60 and 83-155 are not obvious over the combination of Vincent and Furst because (1) one of ordinary skill in the art would not have looked to combine Vincent and Furst, as argued by the Examiner, and (2) even assuming, *arguendo*, that the Examiner properly combined Vincent and Furst in his §103

rejection, the result of this combination would not be the claimed invention because such references, either individually or in combination do not disclose an implantable constriction device for forming a restricted stoma opening in the stomach of a patient that includes an elongate member or elongate means for constricting the stomach of a patient that is surrounded by a base material or means for making the constricting means self-supporting, as recited in independent claims 1, 56, 83, 87, 91, 95, 99, 103, and 107 of the present application.

2. The Combination Of Vincent And Furst Would Not Result In The Claimed Invention

Turning first to the teachings of Vincent, Vincent purports to disclose a gastric band 10 which can be easily placed and fastened into an encircling position around a patient's stomach laparoscopically and which adjusts the constriction of the stoma of the patient's stomach entirely by means of an inflatable member 16. Figure 1 of Vincent depicts the gastric band 10 disclosed by Vincent. The band 10 includes a body portion 11 with an inner stomach-facing surface 15. The body portion 11 has a head end 12 and a tail end 13 with one or more suture holes 13(a) therein. The head 12 of the body portion 11 has a buckle 19 with a pull tab having a suture hole 18(a) integral therewith. A fill tube 14 including a lumen 14(a) is in fluid communication with the inflatable member 16 on the inner surface 15 on the band body 11. Vincent states that an important feature of his gastric band is that the inflatable member 16 is substantially coextensive with the inner surface 15 of the body portion 11. Vincent, col. 2, lns. 33-49.

Thus, it is clear from the description of the gastric band 10 depictured in Figure 1 of Vincent that Vincent does not disclose an implantable constriction device for forming a restricted stoma opening in the stomach of a patient in which the constricting means, *i.e.*, the inflatable member 16 is surrounded by a base material or means for making the body member self-supporting. Rather, as shown in Figure 1 of Vincent, the inflatable member 16 is coextensive with an inner stomach-facing surface 15 of the body portion 11 of Vincent's gastric band 10.

3. One Of Ordinary Skill In The Art Would Not Have Looked To Combine Vincent And Furst

In his §103 rejection, the Examiner acknowledges that Vincent does not disclose a device having property improving means for improving at least one physical property of a composite structure other than self-supporting properties, or the various properties recited in the several independent claims of the present application. To compensate for this deficiency in Vincent's teachings, the Examiner again points to Furst as disclosing "property improving means comprising a coating or layer on a base material at least along a side of said elongate composite structure that is capable of contacting the stomach or esophagus, said coating having better aggressive body fluid resistant properties than said base material, said coating being selected from the group consisting of Teflon™ (polytetrafluoroethylene), Parylene™, and a biocompatible metal coating selected from the group consisting of gold, silver, and titanium, and that biocompatible coatings are used to reduce inflammation, infection, irritation, and/or rejection of the device. 10/3/08 Office Action, page 4.

A. Furst Does Not Compensate For The Deficiencies In The Teachings Of Vincent

Furst purports to disclose an expandable stent for keeping a body passageway open. A stent is an expandable metal tubular device that is mounted over an angioplasty balloon and deployed at the site of coronary narrowing. The balloon is inflated to expand the stent to physically open and return patency to the body passageway. After the stent is expanded, the balloon is deflated and removed and the stent is permanently disposed to retain the opened body passageway. *See* Furst, page 1, paragraph [0005]. Thus, Furst has nothing to do with an implantable constriction device for forming a restricted stoma opening in the stomach of a patient, as claimed in the present application.

B. One Of Ordinary Skill In The Art Would Not Have Looked To Furst Because Furst Is Concerned With Overcoming Biological Problems Not With Improving Physical Properties

Turning next to the combination of Furst with Vincent, one of ordinary skill in the art would not have looked to Furst for a property improving means for improving at least one physical property of an elongate composite structure that is used to constrict a patient's stomach, as recited in the independent claims of the present application, because Furst is concerned with overcoming biological problems encountered with implanting a stent in a body passageway to keep the body passageway open, not with improving the physical properties of the stent.

As noted above, Furst purports to disclose an expandable stent for use within a body passageway. The objects of Furst's invention are listed in paragraph [0011] of Furst, namely, to provide "a stent that has improved procedural success rates, has higher viability

under fluoroscopy in vivo, retains its longitudinal dimensions from its original pre-expanded configuration to its expanded configuration, minimizes damage to tissue during insertion and expansion of the stent, inhibits or prevents the occurrence of in-stent restenosis, vascular narrowing and/or restenosis long after the stent has been inserted into a body passageway, and is simple and cost effective to manufacture. Furst, pages 2-3, paragraph [0011].

According to Furst, these objects are attained by, among other things, providing the stent with a biocompatible coating that can be used to reduce inflammation, infection, irritation and/or rejection of the stent, Furst, page 5, paragraph [0017], or with a coating of one or more vascular active agents that inhibit and/or reduce restenosis, vascular narrowing and/or in-stent restenosis, Furst, page 6, paragraph [0024].

Furst defines (1) "in-stent restenosis" as where a body passageway, which has been previously treated with a stent, renarrows or closes within the stented segment, (2) "vascular narrowing" as a vascular segment that has not been previously treated by any interventional means and eventually closes, thereby preventing fluid body passageway, and (3) "restenosis" as the renarrowing of a previously treated vascular segment not involving a stent. Furst notes that "[v]ascular narrowing, restenosis and in-stent restenosis are caused by biological factors causing the premature closing of the body passageways." Furst, page 2, paragraph [0009].

Furst defines a "biological agent" as:

> any substance, drug or otherwise, that is formulated or designed to prevent, inhibit and/or treat one or more biological problems, such as, but not limited to, viral, fungus and/or bacteria infection; vascular disorders; digestive disorders; reproductive disorders;

> lymphatic disorders; cancer; implant rejection; pain; nausea; swelling; arthritis; bone disease; organ failure; immunity diseases; cholesterol problems; blood diseases; lung diseases and/or disorders; heart diseases and/or disorders; brain diseases and/or disorders; neuroglial diseases and/or disorders; kidney diseases and/or disorders; ulcers; liver diseases and/or disorders; intestinal diseases and/or disorders; gallbladder diseases and/or disorders; pancreatic diseases and/or disorders; psychological disorders; respiratory disorders; gland disorders; skin diseases; hearing disorders; oral disorders; nasal disorders; eye disorders; fatigue; genetic disorders; burns; scars; trauma; weight disorders; addiction disorders; hair loss; cramps; muscle spasms; tissue repair; and/or the like.

Furst, page 8, paragraph [0029]. As such, Applicant concludes that the problems solved by Furst are directed to vascular matters and biological problems, and not improving the physical properties of an implant, such as a stent.

C. One Of Ordinary Skill In The Art Would Not Look To Document Concerned With Stents To Solve A Problem With Gastric Banding

Applicant further asserts that because the problems experienced with a stent are remote from the problems experienced with a gastric band, a person of ordinary skill in the art would never look to document concerned with stents to solve a problem with gastric banding. The present invention relates to a constriction device for forming a restricted stoma opening in the stomach of a patient. No such application is disclosed in Furst. Furst discloses a stent provided with a biocompatible coating. *See* Furst, page 5, paragraph [0017]. The stent is expanded after insertion into a body passageway and is never restricted. The main objective of Furst is to keep the passageway open. This objective is attained by providing the biological agent inhibiting and/or reducing restenosis, vascular narrowing

and/or in-stent restenosis. *See* Furst, page 8, paragraph [0030]. The present invention has nothing to do with restenosis or vascular narrowing. The present invention is related to restricting an opening. Furst is related to keeping an opening open. Given these differences, Applicant further asserts that a person of ordinary skill in the art would not have looked to Furst as relevant prior art when assessing the problems solved by the claimed invention of the present application, and thus, would not have combined Furst with Vincent in an effort to produce the claimed invention. A Rule 132 Declaration of Dr. Peter Forsell, the named inventor and applicant in this application, was submitted as Attachment A with the Amendment After Final Rejection filed last August 13, 2008 in support of these assertions. Presumably, the Examiner did not specifically address this Declaration in the October 3, 2008 Office Action because of the new grounds for rejection set forth in such Office Action.

Applicant further notes that claims 1, 17, 56, 58, 83, 84, 87, 88, 91, 92, 95, 96, 99 100, 103, 104, 107, 108, 112, 117, 122, 127, 132, 137, 142 and 155 have been amended to delete the term "esophagus". As such, only "stomach" remains as an application area for the constriction device described in these claims.

Furst teaches the use of a stent in an exhaustive list of application areas:

> A "body passageway" in an animal or human includes, but is not limited to, the bile duct, bronchiole tubes, blood vessels, the esophagus, trachea, ureter, urethra, the intestines, lymphatic vessels, nasal passageways, and/or the like. The invention when used in association with stents is particularly applicable for use in blood vessels, and will hereinafter be particularly described with reference thereto."

Furst, page 3, paragraph [0012].

> For example, the expandable stent may be used for, but not limited to, such purposes as 1) a supportive stent placement within a blocked vasculature opened by transluminal recanalization, which are likely to collapse in the absence of an internal support; 2) forming a catheter passage through mediastinal and/or other veins occluded by inoperable cancers; 3) reinforcement of catheter created intrahepatic communications between portal and/or hepatic veins in patients suffering from portal hypertension; 4) supportive stent placement of narrowing of the esophagus, the intestine, the ureter and/or the urethra; and/or 5) supportive stent reinforcement of reopened and previously obstructed bile ducts. Accordingly, use of the term "stent" encompasses the foregoing usages within various types of body passageways, and also encompasses use for expanding a body passageway.

Furst, page 13, paragraph [0058].

Applicant contends that it is impossible to insert into a human body a stent having the properties, such as diameter, allowing support of the stomach in order to keep it open. This supports a conclusion that Furst would not suggest to one of ordinary skill in the art to look to the stent described in Furst to solve problems associated with restricting a patient's stomach to treat obesity. Thus, Furst does not teach in the direction of the claimed invention.

D. The Examiner Must Provide "Concrete Factual Evidence" To Support His Determination That The Rejected Claims Are Not Patentable Because They Are Obviousness

In arguing, in his §103(a) rejection of claims 1, 17-19, 56, 58-60 and 83-155, that "[a]lthough Furst does not teach a property improving viscoelastic layer, it would have been obvious to one of ordinary skill in the art to provide a layer surrounding the device made of a biocompatible material that reduces the likelihood of injuring or damaging tissue upon

contact, such as silicone gel, cellulose gel, or collagen gel," the Examiner seeks to compensate for the acknowledged deficiency in Furth of not disclosing the claimed viscoelastic layer, by arguing, without any support in the record, that it would have been obvious to use a viscoelastic layer to reduce the likelihood of injuring or damaging tissue upon contact by the constriction device. 10/3/08 Office Action, page 5.

However, in the case of *In re Zurko,* 258 Fed.3d 1379, 1385-86 (Fed. Cir. 2001), the Federal Circuit held that an Examiner must provide "concrete factual evidence" to support his determination that claims are not patentable because they are obviousness over cited prior art. The same is true with respect to the Examiner's §103(a) rejection of claims 1, 17-19, 56, 58-60 and 83-155 over Vincent and Furst. Thus, it is not proper for the Examiner to rely on an unsupported assertion that it would have been obvious to use a viscoelastic material to reduce the likelihood of injuring or damaging tissue upon contact to support his §103(a) rejection of such claims.

For the reasons discussed above, it is clear that claims 1, 17-19, 56, 58-60 and 83-155 are not obvious over the combination of Vincent and Furst.

In view of the foregoing, it is believed that all of the claims remaining in the application, *i.e.*, claims 1, 17-19, 56, 58-60 and 83-155, are now in condition for allowance,

which action is earnestly solicited. If any issues remain in this application, the Examiner is urged to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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MEMORANDUM

DATE: **May 3, 2007**

TO: **Technology Center Directors**

FROM: **Margaret A. Focarino**
Deputy Commissioner
for Patent Operations

SUBJECT: **Supreme Court decision on *KSR Int'l. Co., v. Teleflex, Inc.***

The Supreme Court has issued its opinion in *KSR*, regarding the issue of obviousness under 35 U.S.C. § 103(a) when the claim recites a combination of elements of the prior art. *KSR Int'l Co. v. Teleflex, Inc.*, No 04-1350 (U.S. Apr. 30, 2007). A copy of the decision is available at http://www.supremecourtus.gov/opinions/06pdf/04-1350.pdf. The Office is studying the opinion and will issue guidance to the patent examining corps in view of the *KSR* decision in the near future. Until the guidance is issued, the following points should be noted:

(1) The Court reaffirmed the *Graham* factors in the determination of obviousness under 35 U.S.C. § 103(a). The four factual inquiries under *Graham* are:

(a) determining the scope and contents of the prior art;
(b) ascertaining the differences between the prior art and the claims in issue;
(c) resolving the level of ordinary skill in the pertinent art; and
(d) evaluating evidence of secondary consideration.

Graham v. John Deere, 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966).

(2) The Court did not totally reject the use of "teaching, suggestion, or motivation" as a factor in the obviousness analysis. Rather, the Court recognized that a showing of "teaching, suggestion, or motivation" to combine the prior art to meet the claimed subject matter could provide a helpful insight in determining whether the claimed subject matter is obvious under 35 U.S.C. § 103(a).

(3) The Court rejected a rigid application of the "teaching, suggestion, or motivation" (TSM) test, which required a showing of some teaching, suggestion, or motivation in the prior art that would lead one of ordinary skill in the art to combine the prior art elements in the manner claimed in the application or patent before holding the claimed subject matter to be obvious.

(4) The Court noted that the analysis supporting a rejection under 35 U.S.C. § 103(a) should be made explicit, and that it was "important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements" in the manner claimed. The Court specifically stated:

> Often, it will be necessary . . . to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an **apparent reason** to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis **should be made explicit**.

KSR, slip op. at 14 (emphasis added).

Therefore, in formulating a rejection under 35 U.S.C. § 103(a) based upon a combination of prior art elements, it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed.